

REMARKS

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action.

Status of the Claims

Claims 34-36, 38, 54-56, 59 and 61 are amended. Claim 64 is new. Support for the new and amended claims may be found, for example, at paragraph [0014], [0030] in light of the Examples, and [0047] of the originally filed specification.

Claims 37 and 39-53 have been canceled.

Claims 34-36, 38, and 54-64 remain in this application.

Claim Objections

Claims 36, 37, 40, 42, 45, 46, 48 and 55 were objected because of informalities.

Claims 37, 40, 42, 45, 46, and 48 are cancelled.

Claims 55 and 36 are amended to correct the informalities.

Therefore, withdrawal of the objection is respectfully requested.

Claim Rejections-35 USC §112

Claim 48 was rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is moot, as the claim is cancelled.

Claim Rejections-35 USC §102

Claims 34-47 and 49-53 were rejected under 35 U.S.C. §102(b) as being anticipated by KATSUHIRO et al. JP 2002-180110 ("KATSUHIRO"). This rejection is respectfully traversed for the reasons below.

The claimed invention is directed to a colloid solution of metal particles or metal compound particles for use in an integrity test for a virus removal membrane, the method of preparing the particles and the method of using the particles in the integrity test. The colloid solution comprises (1) metal or metal compound particles having average diameters of 15-40 nm and being formed of one metal, (2) a water-soluble high molecular weight dispersant containing a pyrrolidone group, (3) water, and (4) an anionic surfactant and/or a chelating agent. The colloid solution has particular maximum absorption wavelength properties.

KATSUHIRO fails to disclose the claimed invention with respect to at least two features:

(1) KATSUHIRO requires the combination of two metal salts (A) and (B) whose standard hydrogen electrode potentials are different. KATSUHIRO discloses that the colloid consists of metal (B) being contained in metal (A) with desired ratio (0.001 - 0.010).

(2) KATSUHIRO discloses that surfactant agents include polyvinylpyrrolidone (PVP) and surfactant agents and others

(0012). However, KATSUHIRO fails to disclose these agents in combination.

Thus, KATSUHIRO fails to anticipate the claimed invention.

KATSUHIRO also fails to render obvious the claimed invention.

Most significantly, KATSUHIRO teaches away from the claimed invention, as KATSUHIRO discloses that when the colloid is prepared with only one 100% metal (A), the metal condenses and a metal colloid having excellent dispersibility cannot be obtained (paragraph 0024). Further, KATSUHIRO fails to disclose or suggest the combination of a water-soluble high molecular weight dispersant containing a pyrrolidone group and an anionic surfactant and/or a chelating agent.

Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §103

Claim 48 was rejected under 35 U.S.C. §103(a) as being unpatentable over KATSUHIRO in view of MELTZER et al. 1998 ("MELTZER"). As claim 48 is cancelled, this rejection is moot.

Claims 54 and 56-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over MELTZER in view of KATSUHIRO. This rejection is respectfully traversed for the reasons that follow.

MELTZER

MELTZER discloses that the integrity of a virus removal membrane is measured by a particle challenge test using dextran, PVP or colloidal gold. However, while MELTZER uses PVP as a standard material for examining permeability of the membrane, MELTZER fails to disclose or suggest the use of a water-soluble high molecular weight dispersant containing a pyrrolidone group as utilized by the integrity test method of claim 54.

MELTZER discloses that HIRASAKI relates to a particle challenge test using colloidal gold. The method for preparing colloid solution used in HIRASAKI is based on ISURUMI. (See, e.g., *EXPERIMENTAL Monodisperse Gold Particles* of page 1245 of HIRASAKI, which is provided in the appendix of this amendment.) TSURUMI discloses that PEG with a molecular weight of 20000 was used as an agent for stabilizing dispersion of gold colloid. (See, e.g., *EXPERIMENTAL Monodisperse Gold Particles* of page 305 of TSURUMI, which is provided in the appendix of this amendment.)

However, PEG is not enough for the stabilizing agent. As evidenced by table 3 of the present specification, which compares Example 3 with Comparative Example 3, a water-soluble high molecular weight dispersant containing a pyrrolidone group, such as PVP, is better than PEG as a stabilizing agent for colloidal solutions.

Indeed, a metal colloid solution exhibiting the claimed excellent pH and storage stability and the claimed integrity test method exhibiting high recovery rate is achieved by the combined use of a water-soluble high molecular weight dispersant containing a pyrrolidone group, such as PVP, and an anionic surfactant and/or a chelating agent. MELTZER fails to disclose or suggest these results.

MELTZER also fails to disclose or suggest the claimed type of membrane recited in claim 56. MELTZER discloses a filtration membrane exhibiting low protein adsorption, such as cellulose acetate, modified polyethersulfone and modified PVDF. There is no disclosure or suggestion of a membrane integrity test using a metal colloid carried out on a thermoplastic synthetic polymeric membrane of which the surfaces were hydrolyzed.

Thus, MELTZER fails to disclose or suggest both the claimed colloid solution utilized in the independent claim 54 and the specific membrane tested in claim 56.

KATSUHIRO

KATSUHIRO fails to remedy the shortcomings of MELTZER for reference purposes.

As discussed above with respect to the anticipation rejection, KATSUHIRO fails to disclose or suggest the combination of a water-soluble high molecular weight dispersant containing a pyrrolidone group and an anionic surfactant and/or a chelating

agent. There is no suggestion of the effects of such a combination, e.g., the claimed colloid solution properties, or excellent storage stability and pH stability, and the claimed integrity test method with a high colloid recovery rate.

KATSUHIRO also fails to disclose or suggest an integrity test method that uses a colloid solution. KATSUHIRO merely discloses using a colloid solution for various catalysts and electromagnetic materials (see, e.g., [0033]-[0034]). There is no discussion about the reduction in interaction between membrane materials. Thus, KATSUHIRO fails to provide any guidance for using the metal colloid solution as a standard material for examining the permeability of a membrane in an integrity test for the membrane.

Furthermore, as also discussed previously, KATSUHIRO teaches away from a colloid solution comprising particles or compounds formed from one metal. Thus, one of ordinary skill in the art would have been strongly discouraged from looking to KATSUHIRO for guidance to modify the exemplified colloid gold particle solution of MELTZER.

Therefore, the proposed combination fails to render obvious claims 54 and 56-61, as well as new claim 64, and withdrawal of the rejection is respectfully requested.

Claims 55 and 62-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over TATEISHI et al. 2001

("TATEISHI") in view of NAOKI et al. JP 2002-060805 ("NAOKI").
This rejection is respectfully traversed for the reasons below.

Claims 55, 62 and 63 now depend from claim 54, and, thus, as acknowledged by the Official Action, the combination of TATEISHI and NAOKI fails to teach or suggest the claimed invention.

Indeed, NOAKI is contrary to the claimed invention as NOAKI requires metallic particles formed from two or more metals.

Therefore, the combination fails to render obvious claims 55, 62 and 63 of the claimed invention, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- HIRASAKI et al., Polymer Journal, Vol. 26, No. 11,
pp. 1244-1256 (1994) ("HIRASAKI")
- TSURUMI et al., Polymer Journal, Vol. 22, No. 4,
pp. 304-311 (1990) ("TSURUMI")